

Title: "ED Disability Diagnostic Tool: an HIT Feasibility Study"

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^β This study is dedicated to Dr. Thomas L. Conner who passed away less than one month after the conclusion of the analyses. Dr. Conner's vision and inspiration guided the research and the results. The results of this study will improve the lives of geriatric patients nationally. Dr. Conner would find such joy in impacting the world yet once again so positively. His wisdom, friendship, and advice will be deeply missed.

ABSTRACT

Purpose: The purpose of this study was to develop a screening tool and prognostic score with superior psychometric properties for geriatric patients presenting to the ED.

Scope: The metrics, costs, and prognostic score were created through a retrospective and two prospective cohorts including an RCT of geriatric patients receiving CMS to identify geriatric patients with cognitive and physical disabilities.

Methods: This multi methodological study included deriving a Rasch scale of disability: I) Using the RDDT to retrospectively score disability indicators, validating the RDDT, selecting a subset of the Rasch scale to be used as a brief measure for an ED randomized clinical trial; II) Prospectively, linking disability assessments to patient oriented outcomes (health care service utilization and mortality). This study compared cognitive and physical disability scores along with prognostic score to determine impact on patient outcomes and costs.

Results: We were able to successfully develop a screening and prognostic score based on study results. We also developed a health informatics tool application to work in a fast paced high volume ED. The average screen took only 90 seconds.

<http://www.edgrayweb.com/>

Key Words: Geriatric admissions, cognitive and physical disabilities, disability screening, prognostic score,

Purpose (Objectives of the study)

The purpose of this study was to improve health outcomes for geriatric patients presenting to emergency departments (EDs) by developing and testing a disability diagnostic tool. We went through a series of Rasch analyses to establish which sets of information were in fact unidimensional and formed usable scales. We tested the validity of the preliminary version of the screening tool on existing hospital data by using it to predict health outcomes. Finally, we consulted the panel of experts to determine which information items, if any, were essential or missing from each content area. If there were such items they were added to the tool. Previous measures of disability were used for persons in long term care (LTC) and thus, were not relative to geriatric patients in the ED. We needed to validate our new screening and prognostic tool for use in the ED. The retrospective analysis determined which indicators had superior measurement properties for use in the ED, plus, the retrospective analyses linked ED patient disability to health outcomes which is a necessary external validation step. A modified screening tool was used in the prospective phase of the study.

To this end, the overarching objective of this study was to improve geriatric patient health outcomes presenting to EDs by developing, validating, and testing a disability screening and prognostic tool in a randomized clinical trial. Here is the link to the final tool: <http://www.edgrayweb.com/>

Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

As more Americans reach old age, the demand for health care increases at an alarming rate often outpacing service availability.(1-4) Lacking resources and options, many elderly patients present to the Emergency Department (ED) often for nonemergency conditions.(5-7) Persons over 75 years have a high ED visit rate at 60.2 visits per 100 persons, accounting for 10.2 million visits annually. Elderly patients over 65 years are disproportionately admitted to the hospital from the ED. (8) A significant proportion of hospital admits results in deleterious outcomes unrelated to the cause of the original presentation (9) such as an increase in infectious disease, disorientation, and risk of falls due to an unfamiliar environment.(10-12)

ED physicians do not have sufficient tools or knowledge to assess geriatric patients.(13) Current disability measures used in long term care settings to assess functional and cognitive status are unreliable and invalid in the ED. This is a significant healthcare problem for multiple reasons. First, discharged patients with low functional status and no referral return to the ED repeatedly.(14-16) A proper diagnosis will lead to a better course of action and referrals which will indirectly improve health outcomes while preventing costly and unnecessary ED visits, or costly and non-covered social admits or admits without a definitive diagnosis.(15, 16) Second, Medicare declines payment for patients admitted to the hospital without an admissible diagnosis, leaving patients and hospitals financially responsible for exorbitant health care expenditures.

High readmission rates may be related to inadequate coordination of care and poor discharge planning. (17) Third, ED physicians are more likely to make a “social admit” for lack of health care options, because these patients’ low functional status prevents them from returning to and thriving in the community. Finally, archaic systems of disability assessment involve manually recording information, manually entering those data into the hospital system, and then re-entering the same data into a referral system. This is accomplished in an already-crowded ED, further increasing the likelihood of human error. Better brief ED assessments of disability in an HIT platform are desperately needed to properly assess elderly patients and to provide health care that serves the patient’s needs yet remains cost-effective.

Setting - Yale-New Haven Hospital is an urban, tertiary care center that is designated as a Level 1 Trauma Center. This study will rely on existing hospital records for the retrospective phase and the ED patient population (Medicare recipients) for the prospective phase. There are approximately 72,000 adult ED visits each year. The population of the primary catchment area is 350,000 and includes a diverse ethnic and cultural mix. Women and minorities are strongly represented in the population. Women represent approximately 51% of the ED population. The racial mix is approximately 50% White, not of Hispanic Origin; 33% Black, not of Hispanic Origin, 15% Hispanic; 1% Asian and 1% other. The ED is staffed by full time physicians from the Yale School of Medicine, Nurse Practitioners from the Yale School of Nursing, resident physicians from Yale-New Haven Hospital, and Yale-New Haven Hospital nursing, social work and administrative staff.

1. Participant, Incidents, Prevalence: Approximately 72,000 patients are evaluated annually at the YNHH-ED of which 56% are women; 30% are African American, and 17% Hispanic. Based on this prior ED studies performed by this research team and the number of persons requiring disability assessments, we did not anticipate any difficulty in recruiting or reaching the target sample size in the 3.5 year enrollment period (see sampling). Based on the power analyses, we easily recruited 600 subjects at random. The prospective phase of the study involved comparing the old methods of evaluating disability to the RDDT. We compared how each measure predicted disability and health outcomes. Power required 400 subjects. Our target sample of 600 allows for 10% attrition.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Design

Retrospective Study - As noted measures of functional and cognitive disabilities are either not used or not well designed in US EDs. Thus, this study remedied the deficit in clinical practice and the literature by creating a better tool to assess disabilities and improve health outcomes for ED geriatric patients. We used Rasch techniques to derive a better measure of functional and cognitive disabilities. Our Hypothesis was that Rasch

modeling would provide an instrument with better measurement properties, including increased reliability and validity compared to currently available instruments. These results are published and there was a positive finding.

The first step in constructing the RDDT was to convene our research experts in measurement, disabilities, emergency medicine, and geriatric medicine (including social workers, nurse practitioners) to finalize the indicators for each of the dimensions of disability. We psychometricians created a scale that was theoretically scalable. We developed rating criteria and used hospital records to rate disabilities in the retrospective portion of this study.

Data Source - LYNX - ED records have been kept at YNHH using the Lynx medical record system (Lynx Medical Systems, Bellevue WA, www.lynxmed.com) from April 2005 to the present. (NOTE: Yale did NOT yet have an electronic medical record system at the inception of this study) This is a hybrid system built specifically for ED documentation, storage, and retrieval, in which a templated paper record with fields based on the chief complaint, is generated for each patient. The providers, including consultants and nursing staff, filled out a paper record which was then scanned into the patient record by associating the bar code at the bottom with the patient and stored as a portable document format (PDF, International Organization for Standardization, www.iso.org). Records were retrieved and viewed remotely via the web, and were searchable by patient name, date, chief complaint, and location of treatment. The Lynx system automatically displayed additional ED visits for the same patients. The Lynx system had several attributes that made it ideal for retrospective research. As a templated paper record it prompted clinicians for standard aspects of the history and physical examination that were tailored to complaints and were fairly consistent for patients with a disability (dizziness, confusion, weakness, inability to stand). It had the flexibility for the provider to write and diagram, and while extracting certain discrete data points was more labor intensive than it might be for a true electronic medical record (EMR) it allowed for more broad inclusion of patient documentation.

Medical Record Review - The RAs obtained data by using the Lynx charting system into our electronic secure data collection system. All data were available via the internet from secure computers in the Department of Emergency Medicine offices, and RAs were provided dual monitor setups to allow accessing and entry of data. The Lynx ED chart typically includes all written data from the ED visit, pre-hospital documentation, triage and RN documentation, mid-level provider and physician documentation, ancillary services, and consultants. The entire written ED record was reviewed with data gathered where it was available. If discrepant information was present but clearly documented, the most senior level documentation was used, unless it was contradicted in more than one place.

Scale Validation – I performed the standard scale validation procedures including item analysis (scale is related or predicts item responses), external validation (persons

scoring high in disabilities should have worse health outcomes), and reliability analysis. After, I ran Rasch analyses that had implicit validation procedures as well. We increased reliability over existing measures. We statistically and theoretically selected a subset of indicators that remained accurate and precise to use in the prospective phase of this study as a brief RDDT.

Eligibility Inclusion Criteria: Patients who presented to the adult ED at the Yale New Haven Hospital (YNHH) were: (1) 65 years or older (2) and Medicare recipients (3) community dwellers.

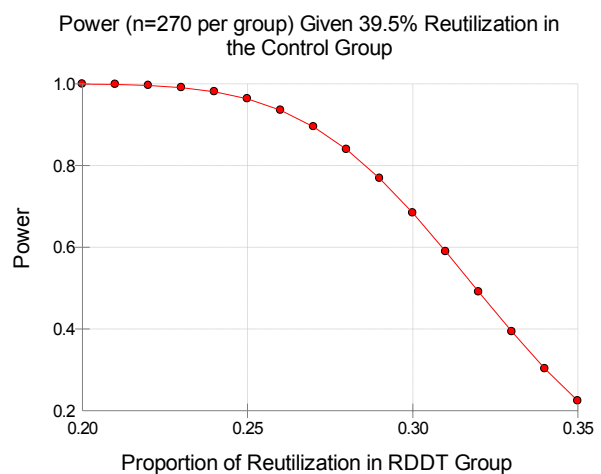
Exclusion Criteria: Patients and their guardians were excluded for the following reasons: (1) Non English speaking (2) suffering from a condition that precludes interview i.e. communication impairment (3) unable to provide two contact numbers for follow-up (4) presenting with acute psychosis or are suicidal.

Patient Screening: Privacy and confidentiality were a priority. The Emergency Department does not afford privacy for subjects. Thus, study participants will be brought into a private interview room in an area adjacent to the ED and removed from the usual chaos of an ED. Patients will only be asked to participate when family members and friends are not present unless the patient is under the guardianship of another family member. Eligible patients were screened using the screening form based on inclusion and exclusion criteria.

Prevalence and Incidence: Sample size calculations were performed using the pooled Z-test for two independent proportions module of PASS version 2005 (Kaysville, UT). A review of our census over the last year has shown that 29.5% of our patients above the age of 65 have return visits to our ER within 2 months.

Baseline Assessments Collected at Index Visit

1. **Disability Assessment:** Brief assessment
2. **Demographic information:** included standard questions about age, gender, cultural/ethnic group, educational level, marital status, employment, and additional insurance.
3. **Clinical and Presenting History** – Chief complaints for ED presentation
4. **Short Form Health Survey (SF-12)** - This was used to assess health status. The SF-12 assesses health in two domains, physical summary measures and overall general health perceptions. Reliability and validity was established in patients from the Medical Outcomes Study.(18)



5. **Cohen Social Support Index** - Which includes multiple items asking about various types of emotional support and various types of instrumental/informational support. (19)
6. **Social Support network** – who patient lives with, guardianship, friends, family, or independent.
7. **Holmes and Rahe Stress Scale**- 43 item measure of stressful life events that impact health. (20)

Formal follow-up assessments are planned 30 days after the index visit.

Primary Outcome Measures

8. **Health Service Utilization Access** –including all-cause related hospitalization, ED visits and testing using the treatment services review (TRS) (21) was used to obtain this information (described below).
9. **Mortality**: data were collected from health care records and/or guardian proxies.

Secondary Outcome Measures

10. **Quality of Life**: was measured using the Health Form SF-36 (22)
11. **Health Well Being**: Long-term care placement, injuries from falls or car crashes, malnutrition, personal upkeep, wandering.

Limitations: Some patients were too sick or ineligible to participate in the study including:

Data Collection Sources:

Data were collected from the following sources: (1) LYNX: Described above. (2) Health care provider (3) Interviews: were conducted by the RA to complete data collection. (4) Patient and/or guardian administered instruments.

Statistical Methods: Data analyses were conducted in collaboration with the Biostatistics Unit of the Yale Center for Clinical Investigation. For all analyses, a type I error of 5% (two-sided) was used to test for statistical significance and was performed using SAS v9.1 (SAS Institute, Cary, NC) and Rasch analysis using WinSteps

Aim 1: To develop and validate an Emergency Department (ED) Rasch Disability Diagnostic Tool (RDDT).

Hypotheses: 1a. . Rasch modeling provided an instrument with better measurement properties, including increased reliability and validity compared to currently available ED MOD. (See first two publications for evidence.

Aim 2: To conduct a randomized controlled trial to evaluate the utility of the ED-RDDT to reduce rehospitalizations in Medicare recipients visiting an urban Emergency Department for non-traumatic illness

Hypotheses:

2a. Compared to the standard screening tool, the ED RDDT will reduce reutilization of the hospital (ED visits, hospital admissions or death) within 30 days of discharge.

2b. The ED RDDT reduced costs to Medicare, hospitals and patients.

Analyses Aim 2: Preliminary analyses included descriptive statistics for baseline and follow-up data. Baseline characteristics were compared between groups using t-tests for continuous variables and chi-square tests for categorical variables. Efficacy analyses was used with the intent to treat convention in which all randomized subjects are included in the group to which they were randomized.

Aim 2a: The primary outcome for this aim is a composite of re-utilization of the ED, hospital admission or death within 30 days of the initial ED visit. Each participant will be classified for this binary outcome as either experiencing the event or not. We hypothesized that the proportion of the participants experiencing the primary outcome was less in those that have received the ED-RDDT intervention compared to those that received the current MOD. Logistic regression was used to compare these proportions across groups. The 3 stratification factors, shift, day of week and calendar year quarter were included as categorical covariates in the regression. Poisson regression also was employed to evaluate the number of hospital or ED re-utilizations over the 30 day period. Alternative models (eg. negative binomial, zero-inflated poisson) were employed when outcomes were not compliant with a poisson distribution (Lachenbruch). Subgroup analysis by age group (i.e. 65-75, >75) was used to assess for effect modification.

Aim 2b - The project cost-effectiveness analyses was conducted from the perspectives of the hospitals and health care system, respectively. If the control group (MOD) and the treatment group (RDDT) realized the same health outcomes, a cost-effectiveness analysis was conducted. For those interventions in which health outcomes differ, a cost benefit analysis was completed. The methods for quantifying the economic benefits of the RDDT will seek to quantify the benefits of the following (See above for cost outcomes):

- Benefits from more appropriate referrals
- Reductions in ER visits
- Reduction in unnecessary ED admits (admits that do not improve the health outcome relative to outpatient treatment or an office visit)
- Reductions in social admits to hospital from ED

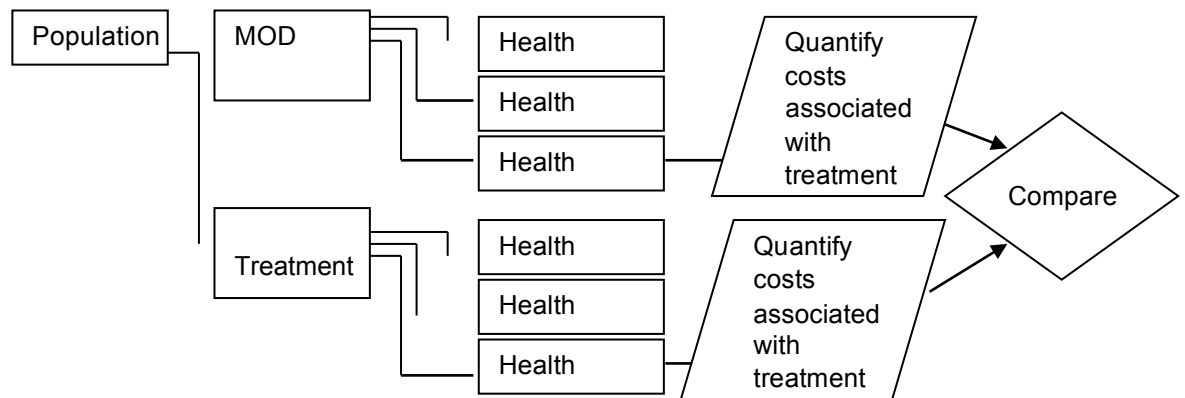
- Reductions in Medicare declinations
- Reductions in patient costs
- Reductions in costs to hospital

The first benefit relates to improved care and better health outcomes. The last five benefits are in fact reduced costs: four related to the medical system and one related to patient costs. In each case ED cost reduction must be calculated net of the costs to other parts of the medical system, e.g. costs of office visits. A complete societal benefit-cost analysis is beyond the scope of this project.

A schematic of the economic evaluation approach is outlined in the figure below. The approach focused on the type of presentations in the ED (sub-populations), e.g. it is common for older patients to present to the ED after a fall. For this sub-population, there may be two or more treatment options. For example, after a minor fall with no broken bones or internal organ damage, the patient may be treated for injuries and released (treatment #1). Alternatively, the patient may be treated for injuries and referred to a physical therapist for balance and coordination therapy (treatment #2). The choice of treatment will depend in part on the physician’s assessment of the patient’s ability to cope with activities of daily living without falling. The RDDT will provide additional information on this issue. Thus, the treatments are expected to differ between the control group and the RDDT group (If the treatments are the same, the economic analysis moves to the next subpopulation).

Hybrid Focus Group/Usability Evaluation (has performance metrics and subject ease-of-use ratings)

A usability specialist will conduct a group exercise with up to nine representative end users to



determine how well the website meets user expectations for navigation, ease of use and functionality. Based on client input, participants perform eight-to-ten tasks using a customized data collection template, recording their time, paths and perceptions. The usability specialist then leads the group in a discussion of their experiences, focusing on tasks that have caused difficulty. This approach enables clients to gather a substantial

amount of quantitative information in a short amount of time, while also offering savings over traditional, one-on-one evaluations.

Usability Focus Groups (feedback from representative users; no performance metrics, but we can gather subjective ratings of ease-of use, user interface architecture flow, and usefulness)

Usability focus group sessions are face-to-face conversations with a group of 8-10 users who provide feedback on website design. There will be two types of groups: sessions that focus on design concepts and sessions that focus on design executions. In the first case users do not complete tasks, but instead gather to discuss their design preferences and assessment content needs. Paper prototypes or conceptual drawings may be referenced. The second type includes the walk-through of a number of typical tasks on a prototype RDDT, followed by group discussion. In both cases, participants (prospective users) provide feedback on the components of an “ideal” program. The usability and accessibility HIT consultant will provide a detailed report with actionable recommendations.

User Interface Review (expert review; no performance metrics)

A group of two-three usability experts performed a “heuristic evaluation,” which is a systematic inspection of the website user interface using a structured walkthrough process, judging compliance with recognized usability principles, called heuristics. Our user interface review will be based on Jakob Nielsen’s 10 heuristics, which are widely recognized within the professional design and usability communities (http://www.useit.com/papers/heuristic/heuristic_list.html). Strengths, weaknesses, and opportunities for improving aspects of the website, ranging from navigational linkages and screen layout to the overall flow of primary user workflows, will be identified. The value of expert user interface reviews is that major usability issues can be caught before the development team commits significant resources to the implementation phase. The report will include results and recommendations that can be used to shape design decisions for future releases.

Accessibility Compliance Inspection (expert review; no performance metrics)

Two accessibility experts will evaluate the website and identify the improvements needed to ensure legal compliance with Section 508 standards and Web Content Accessibility Guidelines (WCAG) 1.0. Coding for accessibility will enhance the user experience of customers who use assistive technology as they interact with the site, web application, or software interface, thus increasing the site’s ability to reach and satisfy the broadest possible audience. Additionally, including common accessibility features will dramatically improve the user experience for customers using mobile phone browsers, personal digital assistants, and low-bandwidth connections. The

consultant will provide a detailed report outlining accessibility standards, whether they have been met, and recommendations for their repair. Examples of compliant code are also available on request.

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implication)

We were able to create a screening tool for cognitive and physical disabilities for geriatric patients plus we were able to create a prognostic score of death, recidivating to the ED or admit to the hospital in 30 days as listed in multiple places throughout report $p < .000000$. Please see two publications and health application below. We are currently publishing the final prognostic publication with cost benefits of identifying cognitive and physical disabilities. The following questions were used for our application. These few questions are the product of hundreds of tests.

ED GRAY

List of Publications and Products (Bibliography of Outputs) from the study.

Geriatric screening and disability tool: <http://www.edgrayweb.com/>

Post LA, Conner TL, Oehmke JF, Abujarad F, Cooney LM, Brandt C, et al. Development and Validation of the Emergency Department Geriatric Readmission Assessment at Yale (ED GRAY): Part 2, Prognostic Accuracy. *British Journal of Medicine and Medical Research*. 2016;14(1):1.

Post LA, Conner TL, Oehmke JF, Abujarad F, Cooney LM, Brandt C, et al. Development and Validation of the Emergency Department Geriatric Readmission Assessment at Yale (ED GRAY): Part 1, Fundamental Measurement. *British Journal of Medicine and Medical Research*. 2016;14(1):1.

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